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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,371	03/09/2004	Adam J. Katz	30448.77USD1	4480

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EXAMINER	
GARVEY, TARA L	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/797,371	KATZ ET AL.	
	Examiner	Art Unit	
	Tara L Garvey	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *March 9, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-13,36-66,73,74,77-79 and 132-168* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,3-13,36-66,73,74,77-79 and 132-168* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, 73-74, 139-149 and 154 -158, drawn to adipose-derived stem cells and implants containing adipose-derived stem cells, classified in class 435, subclass 325.

II. Claims 36, 37 and 57 as drawn to claim 36, drawn to a method to obtain genetically-modified cell, classified in class 435, subclass 455.

III. Claims 39-48, 57 as drawn to claim 39 and 160-162, drawn to a method of differentiating a cell, classified in class 435, subclass 377.

IV. Claims 49, 54 and 57 as drawn to claim 49, drawn to a method of producing hormones, classified in class 435, subclasses 325 and 405.

V. Claims 50 and 57 as drawn to claim 50, drawn to a method of promoting wound closure, classified in class 435, subclass 325.

VI. Claims 51-53 and 57 as drawn to claim 51, drawn to a method pf promoting neovascularization, classified in class 435, subclass 325.

VII. Claims 55-57 as drawn to claim 55 and 163, drawn to a method of conditioning culture medium, classified in class 435, subclasses 325, 373 and 405.

VIII. Claims 58-59 and 164 drawn to conditioned culture medium, classified in class 435, subclass 405.

IX. Claims 60-65, drawn to a method of culturing a stem cell, classified in class 435, subclasses 325 and 405.

X. Claims 77-79 and 165-168, drawn to a kit for isolating stem cells from adipose tissue, classified in class 435, subclasses 325 and 405.

XI. Claims 132-138, drawn to a method of isolating and differentiating stem cells from adipose tissue, classified in class 435, subclasses 325 and 377.

XII. Claims 150-151, drawn to a method of inducing mesodermal tissue, classified in class 435, subclass 1.1.

XIII. Claim 152, drawn to a method of regenerating or repairing tissue, classified in class 435, subclasses 1.1 and 325.

XIV. Claims 38, 57 as drawn to claim 38 and 159, drawn to a method of delivering a transgene to an animal, classified in class 435, subclasses 325 and 455.

Group I is comprised of multiple inventions, which are the products or methods drawn to a combination of phenotypes which are different and distinct phenotypes which do not render obvious each other and thus are patentably distinct. For example, please choose two phenotypes from claim 3. Applicant must elect a single invention which is the product drawn to a combination of phenotypes to which the claims will be restricted. The applicant must also indicate which claims are readable on the elected invention.

Groups III and X are comprised of multiple inventions, which are the products or the methods drawn to a type of culture medium which are different and distinct mediums

which do not render obvious each other and thus are patentably distinct. For example, please choose a type of medium from claim 40 or 79. Applicant must elect a single invention which is the product drawn to a type of culture medium to which the claims will be restricted. The applicant must also indicate which claims are readable on the elected invention.

Groups XI is comprised of multiple inventions, which are the methods drawn to a cell type which are different and distinct mediums which do not render obvious each other and thus are patentably distinct. For example, please choose a cell type from claim 137. Applicant must elect a single invention which is the product drawn to a cell type to which the claims will be restricted. The applicant must also indicate which claims are readable on the elected invention.

Note: the non-standard format of this restriction, separating the inventions into multi-invention groups drawn to distinct types of products and methods, followed by an election of a single invention drawn to one combination or one disease within the elected multi-invention group was done for the sake of compactness of the communication and clarity, instead of using the more standard format setting forth each invention drawn to each separate agent or element which would require a much longer and less clear communication.

The inventions are distinct, each from the other because of the following reasons:

The stem cells of Group I, the conditioned culture medium of Group VIII and the kit for isolating stem cells of Group X are chemically, biologically, and functionally

distinct from each other and thus one does not render the other obvious. The product of each group is not needed to produce the products of the other groups. Therefore, the inventions of the groups are capable of supporting separate patents.

Inventions of Groups II-VII, IX and XI-XIV are biologically and functionally different and distinct from each other and thus one does not render the other obvious. The methods of Groups II-VII, IX and XI-XV comprise steps which are not required for or present in the methods of the other groups: obtaining a genetically-modified cell (Group II), differentiating a stem cell (Group III), producing hormones (Group IV), promoting wound closure (Group V), promoting neovascularization (Group VI), conditioning culture medium (Group VII), culturing a stem cell (Group IX), isolating a stem cell (Group XI), inducing mesodermal tissue (Group XII), regenerating or repairing tissue (Group XIII) and delivering a transgene to an animal (Group XIV).

Inventions of Group VII and Group XVIII are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the conditioned could be made by another method such as by adding the necessary growth factors to the medium.

Inventions of Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another

materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells could have an alternative us such as to produce hormones.

Inventions of Group I and Group III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells could have an alternative us such as to promoter wound closure.

Inventions of Group I and Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells could have an alternative us such as promote neovascularization.

Inventions of Group I and Group V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells could have an alternative us such as to produce conditioned culture medium.

Inventions of Group I and Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells could have an alternative us such as to deliver a transgene to an animal.

Inventions of Group I and Group VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells could have an alternative us such as to induce mesodermal tissue formation.

Inventions of Group I and Group XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells could have an alternative us such as to regenerate or repair tissue.

Inventions of Group I and Group XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially

different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells could have an alternative us such as to produce a differentiated cell.

Inventions of Group I and Group XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the stem cells could have an alternative us such as to produce a genetically modified cell.

Inventions of Group X and Group XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the kit could have an alternative use such as to culture hematopoietic cells.

Except for the specific relationships described above the inventions of Groups I, VIII, X and Groups II-VII, IX and XI-XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different products of Groups I, VIII, X are not used in or made by the methods of Groups II-VII, IX and XI-XIV.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, by their recognized divergent subject matter and by a their requirement for different searches, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance,

whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tara L Garvey whose telephone number is (571) 272-

2917. The examiner can normally be reached on Monday through Friday 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) (http://pair-direct.uspto.gov) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tara L Garvey
Examiner
Art Unit 1636

TLG

JAMES KETTER
PRIMARY EXAMINER